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UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF INDIANA

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CLERK U.S. DISTRICT COURT
NORTHERN DISTRICT OF INDIANA

SAMUEL TURNER, Plaintiff, v. BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; and BIOMET U.S. RECONSTRUCTION, LLC; Defendants.	Court File No.: 3:13CV 595 **COMPLAINT - JURY TRIAL DEMAND**

CIVIL COMPLAINT

Plaintiff, Samuel Turner, residing at 117 Rainbow Park Drive, Boiling Springs, Spartanburg County, in the state of South Carolina, by and through Plaintiff's attorneys, THE LANIER LAW FIRM, PLLC, upon information and belief, and at all times hereinafter mentioned, alleges as follows:

INTRODUCTION AND SUMMARY OF ACTION

1. For more than five years, Defendants have known that their hip replacement device—the M2A-Magnum Hip Replacement System (hereafter, "Magnum Device")—is prone to fail years before its expected life. They have also known that the implant's metal "ball" and "socket" bearings that make up the hip-joint generate metal debris over time from wear and tear that can spread throughout the patient's surrounding bone and tissue. As a result of these defects, patients that have had the devices implanted have endured, or will endure, unnecessary pain and suffering; debilitating lack of mobility; inflammation, causing damage or death to surrounding tissue and bone; and a subsequent more difficult revision surgery to replace the faulty devices, giving rise to still more debilitation, a prolonged recovery time, and an increased risk of

complications and death from surgery. But rather than recalling the Magnum Device upon receiving notice of complaints made to the United States Food and Drug Administration ("FDA") regarding the defects discussed above, or warning physicians and patients of these risks and precautions such as metal level monitoring, Defendants continued to aggressively market the Magnum Device, claiming it was a safe and effective hip replacement system. Indeed, Defendants sought to capitalize on the problems with the competitor devices by asserting the superiority of the Magnum.

2. Plaintiff's suffering could easily have been prevented. Plaintiff would not have suffered from unnecessary pain and debilitation, as well as the need to undergo subsequent revision surgery, had Defendants taken the affirmative step of recalling the Magnum Device, when dozens of complaints began being made to the FDA regarding the Magnum Device's failures, or had Defendants at least warned the orthopedic surgical community and the public of the dangers of the Magnum Device so that those who had the Magnum Device implanted could be medically monitored for signs of the Magnum Device malfunctioning including loosening and metal debris related injury. Plaintiff seeks redress for Plaintiff's injuries.

3. Plaintiff brings this action under the laws of the state of South Carolina.

PARTIES

4. Plaintiff is over the age of majority and is a citizen and resident of the state of South Carolina. Plaintiff has been injured due to a defective medical prosthesis manufactured by Defendants.

5. Defendant, BIOMET, INC. is, and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business in Warsaw, Indiana 46582.

6. Defendant, BIOMET INC., designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip system that is the subject of this lawsuit.

7. Defendant, BIOMET ORTHOPEDICS, LLC, is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant, BIOMET, INC., an Indiana Corporation with its principal place of business in Warsaw, Indiana.

8. Defendant, BIOMET ORTHOPEDICS, LLC, designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip system that is the subject of this lawsuit.

9. Defendant, BIOMET ORTHOPEDICS, LLC, is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant BIOMET U.S. RECONSTRUCTION, LLC, an Indiana Corporation with its principal place of business in Warsaw, Indiana.

10. Defendant, BIOMET U.S. RECONSTRUCTION, LLC, is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant BIOMET, INC., an Indiana Corporation with its principal place of business in Warsaw, Indiana.

11. Defendants, BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC, are collectively referred to herein as "Biomet" or Defendants.

12. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each defendant was acting within the course and scope of its agency and was subject to and under the supervision of its Codefendants.

13. Upon information and belief, at all times herein mentioned, the employees of all Defendants, their subsidiaries, affiliates, and other related entities, as well as the employees of the Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or

transaction of Defendants, such allegations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the Defendants committed, knew of, performed, authorized, ratified and/or directed such act or transaction on behalf of Defendants while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

15. Venue is proper in the District of South Carolina pursuant to 28 U.S.C. §1961, *et seq*., because a substantial part of the events giving rise to this claim occurred in South Carolina.

FACTUAL ALLEGATIONS

THE BIOMET DEFENDANTS MANUFACTURED AND MARKETED THE MAGNUM DEVICE TO THE PUBLIC, EVEN THOUGH THEY KNEW, OR SHOULD HAVE KNOWN, OF THE DANGER THAT THE MAGNUM DEVICE POSED TO THE PUBLIC.

16. The Magnum Device was developed in order to reconstruct human hip joints that are diseased due to conditions, such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), or fracture. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

17. A total hip replacement implant device typically consists of four separate components: a femoral stem, a femoral head (or ball), a liner, and an acetabular shell (socket). Usually these components are made of metal and plastic.

18. The Magnum Device has only three components: a metal femoral head, a metal taper insert, and a metal acetabulum cup. The metal femoral head can be attached to a femoral stem to complete a total hip replacement. As a result of the use of metal in the ball, taper insert, and socket components, the device is referred to by the industry as a Metal-on-Metal (MoM) Implant Device.

19. These devices were marketed with the claim that they would last much longer than the conventional hip implant with a polyethylene liner. Indeed, Defendants aggressively marketed the Magnum Device as having many advantages over other hip replacements or hip resurfacing systems.

20. When initially released, Defendants promoted the device to surgeons as being "designed specifically to address the issue of wear debris" and held it out as "the right choice for use in young, highly active patients."

21. Later, Defendants promoted the device as "offering improved range of motion and joint stability" and employed gymnast, Mary Lou Retton, to deliver the message in April 2006 for direct-to-consumer print, TV, and radio advertising.

22. Even as other MoM devices came under scrutiny for their high rates of failure over the years, Defendants continued to falsely advertise the Magnum Device as a superior and safe device, citing biased and misleading studies and data indicating that the hip replacement was subject to reduced wear and revision.

23. Defendants' represented that the Magnum Device presented optimal clearance between the "ball" and "socket" components. Further, Defendants represented that the clearance of the Magnum Device was neither excessive nor inadequate.

24. Contrary to what Defendants' marketing campaigns suggest, for many years Defendants have known of the risks inherent in MoM devices, including the Magnum Device and its predecessor metal on metal large diameter implant, the M2A 38, which were causing harm in a high number of patients who received them. Specifically, for several years, the FDA had been receiving complaints that the Magnum Devices prematurely failed in some patients, due to component loosening, dislocation, component wear, and fracture, as a result of the design of the device. In addition, reports were received that the implant's "ball" and "socket"—which are both metal bearings—generate metal debris over time from normal wear, and this debris can spread throughout the surrounding bone and tissue causing severe inflammation and damage.

25. Indeed, since the start of 2006, the FDA has received an increasing number of complaints involving patients in the United States that received the Magnum Devices, with a number of these patients requiring complicated, expensive and painful revision surgeries with a prolonged recovery time. Notwithstanding these complaints, Defendants neither halted sales of the Magnum Device nor warned the public. Instead, they continue to aggressively market the Magnum Device as safe and effective, even though they were on notice of the large number of complaints received by the FDA.

26. Defendants were aware that the British Medicines and Healthcare Products Regulatory Agency (MHRA) and the United States Food and Drug Administration expressed concern about Metal-on-Metal hips and the impact of metal ions and thus Defendants, as part of industry trade groups, participated in discussion of studies of the health effects with other manufacturers during that time period.

27. Despite its knowledge that the Magnum Device was defective, Defendants made several false representations about specific design elements of the Magnum Device that they

claimed made it superior to other more safe hip implants on the market. For example, Defendants claimed that:

(a) "The M2a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo," and

(b) "Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

28. Defendants' reason to conceal the defect in its Magnum Device is clear. Hip implant sales are critically important to Defendants, and the Magnum Device is one of its most profitable products. During the time period relevant to this Complaint, Defendants' management was trying to make Defendants look appealing to investors, and in 2007, they were ultimately purchased by a private equity firm for $10 billion.

29. Defendants were faced with a critical defect in one of its most profitable hip implant systems. Rather than to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery, Defendants chose to pursue corporate profits, at the expense of patient safety, and continued to promote, market, and sell the Magnum Device despite the fact that they knew the product was defective. To this day, Defendants continue to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

30. In 2011, the Australian Orthopedic Association published its annual report on data collected from the Australian National Joint Registry, which tracks surgical revisions of orthopedic devices in Australia (the United States does not have such a registry). The Report showed that the Magnum Device had a yearly cumulative revision rate of 7.2% after seven years,

with a statistical range of 5.3% and 9.7%. This is a much higher revision rate than some other MoM hip replacements.

31. Consequently, in May of 2011, the FDA required Defendants, and other manufacturers, to provide data on levels of metal in the blood of patients implanted with their MoM hip implants due to rising concerns regarding their use. The request followed the release of British studies from March 2010 showing that MoM implants, such as the Magnum Device, are potentially dangerous because they can generate large amounts of metallic debris as they wear over time. Metallic debris has been shown to cause severe inflammatory responses in some patients, resulting in pain in the groin, death of tissue in the hip joint, and loss of surrounding bone. These injuries often require revision surgery to replace the device before its expected expiration.

32. In a systematic review of clinical trials, observational studies, and registries conducted by the FDA and published in the British Medical Journal on November 29, 2011, it was found that MoM hip implants are no more effective than traditional polyethylene-lined implants, and increase the risk of revision surgery. Therefore, MoM hip implants increase the safety risk to patients without providing any benefit over traditional hip implants. Due to this poor risk-benefit profile, sales of the Magnum Device have decreased substantially.

33. As a result of the issues with the Magnum Device, Plaintiff has suffered symptoms including pain, swelling, inflammation, and damage to surrounding bone and tissue, and lack of mobility. As noted above, these symptoms are the result of loosening of the implant, where the implant pulls away from the bone of the hip socket; fracture, where the bone around the implant may have broken; dislocation, where two parts of the implant that move against each other are no longer aligned; and the spread of metal debris generated from wear of the metal

femoral head and metal acetabular cup. For these reasons, revision surgery is necessary to remove the defective Magnum Device. Revision surgery presents enormous risks because it is technically more difficult than the original implanting surgery, the patient has an increased risk of complications and death, and the recovery time is prolonged and more painful than the recovery after the original implanting surgery.

AS A DIRECT AND PROXIMATE RESULT OF BIOMET'S FAILURE TO RECALL THE MAGNUM DEVICE, PLAINTIFF WAS IMPLANTED WITH A MAGNUM DEVICE, AND NOW HAS DEBILITATING PAIN AND WAS REQUIRED TO UNDERGO REVISION SURGERY TO REPLACE THE MAGNUM DEVICE.

34. During all material times, Plaintiff has been a resident of the state of South Carolina.

35. On September 14, 2009, Plaintiff underwent a right total hip replacement surgery performed by Dr. John E. Keith at Spartanburg Regional Healthcare System in Spartanburg, South Carolina and received a Magnum Device.

36. After the surgical implantation of the Magnum Device, Plaintiff suffered symptoms including but not limited to increasingly debilitating pain, discomfort, soreness, dysfunction, and loss of range of motion.

37. Plaintiff additionally suffered the following personal and economic injur(ies) as a result of the implantation with the Magnum Device:

(a) underwent an additional surgical procedure that would not have been needed if the Magnum Device had performed satisfactorily during its expected usual life;

(b) is permanently harmed by severe metal poisoning and metallosis from the metal debris of the Magnum Device;

(c) lost wages and future loss of earning capacity;

(d) incurred medical expenses and will incur additional medical expenses in the future and;

(e) is permanently harmed, because of complications normally associated with a second hip replacement.

38. Subsequently, on June 15, 2010, Plaintiff was required to undergo revision surgery, which was performed by Dr. Anthony Sanchez at Spartanburg Regional Healthcare System in Spartanburg, South Carolina to replace the failed Magnum Device.

39. An employee and/or agent of Defendant provided the Magnum Device to Dr. John E. Keith, who implanted the device on September 14, 2009, the date of the original right hip replacement surgery.

40. Beyond merely providing the device to the surgeon, agents of Defendants were hired by Defendants to aggressively promote, distribute, and sell the Magnum Device.

41. Directors, managers, and sales representatives of Defendants received training and education from Defendants, including orthopedic and surgical training, product design rationale for the Magnum Device, education regarding proper use of the tools to implant the Magnum Device, selection of complementary components to the Magnum Device, and training on how to sell the Magnum Device to surgeons over hip replacements offered by competitors.

42. On numerous occasions, Defendants met with orthopedic surgeons, including, on information and belief, with Plaintiff's orthopedic surgeon, to promote the M2a Magnum Hip Implant. At some or all of these meetings, a representative or representatives of Biomet was present. During these meeting, Biomet assured the orthopedic surgeons, including Plaintiff's orthopedic surgeon, that the M2a Magnum Hip System was safe, effective, was the best product on the market, had an excellent track record, would last longer than traditional hip implants and had a low and acceptable failure rate. Biomet continued to "defend" the M2a Magnum Hip Implant even after they became aware of numerous and serious complications with the M2a Magnum Hip System. Biomet did not reveal (and instead concealed) their knowledge of

numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons, including Plaintiff's orthopedic surgeon.

43. Plaintiff's revision surgery has subjected him to much greater risks of future complications than he had before the revision surgery. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent a original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, *et al*. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

44. Defendants were instrumental in educating Plaintiff's Orthopedic Surgeon regarding claimed advantages of the product, addressing the questions of the surgeon.

45. Had Plaintiff or Plaintiff's surgeon known that the Magnum Device caused injury and had the potential to require revision surgery to remove the device, with no benefit over traditional hip implants, then neither Plaintiff nor Plaintiff's surgeon would have chosen the Magnum Device for the hip implant surgery. Rather, Plaintiff and Plaintiff's surgeon would have opted for the safer and more effective traditional hip implant utilizing a polyethylene liner.

46. As a direct and proximate result of the implantation of the Magnum Device, Plaintiff has suffered significant harm, including but not limited to physical injury and bodily impairment, debilitating lack of mobility, conscious pain and suffering, elevated metal ion levels

and loss of earnings. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial.

47. Plaintiff only recently became aware of the causal link between the injuries he has suffered and any wrongdoing on the part of Defendants due to the faulty and defective nature of the Magnum Device and to the failure of Defendants to properly warn him and his physicians about the Magnum Device's defective and faulty nature. Plaintiff was unable to make an earlier discovery of the causal link despite reasonable diligence because of Defendants' failure to properly warn him and his physicians about the Magnum Device's defective and faulty nature, and their failure to issue any recall or take any other proactive action to date with respect to the injuries being caused to patients that have been implanted with a Magnum Device.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (DESIGN DEFECT)
AGAINST ALL DEFENDANTS

48. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

49. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Magnum Device as hereinabove described that was surgically implanted in Plaintiff.

50. At all times herein mentioned, the Magnum Device was in an unsafe, defective, and inherently dangerous condition for users such as Plaintiff that had the device surgically implanted.

51. The Magnum Device was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

52. At all times herein mentioned, the Magnum Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

53. The Magnum Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff.

54. The Magnum Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

55. Plaintiff's injuries resulted from use of the Magnum Device that was both intended and reasonably foreseeable by Defendants.

56. At all times herein mentioned the Magnum Device posed a foreseeable risk of danger inherent in the design which greatly outweighed the benefits of that design.

57. At all times herein mentioned, the Magnum Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

58. At all times herein mentioned, the Defendants knew, or should have known, that the Magnum Device was in a defective condition, and was and is inherently dangerous and unsafe.

59. At the time of the implantation of the Magnum Device into Plaintiff, the aforesaid product was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

60. Defendants, with this knowledge, voluntarily designed their Magnum Device in a dangerous condition for use by the public and, in particular, Plaintiff.

61. At all times herein mentioned the Magnum Device lacked utility for any group of users, including Plaintiff.

62. The Magnum Device provided no net benefit to any class of patients, including Plaintiff.

63. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

64. Defendants failed to complete adequate pre-market testing and post-market surveillance on the Magnum Device;

65. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

66. Defendants are strictly liable for Plaintiffs' injuries in the following ways:

(a) The Magnum Device as designed, manufactured, sold and supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

(b) Defendants failed to properly market, design, manufacture, distribute supply and sell the Magnum Device;

(c) Defendants failed to adequately test the Magnum Device; and

(d) A feasible alternative design existed that was capable of preventing Plaintiff's injuries.

67. As a direct and proximate result of Defendants' placement of the defective Magnum Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as an additional revision surgery to replace the device with the increased risks of complications and death from such further surgery. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

68. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY (FAILURE TO WARN)
AGAINST ALL DEFENDANTS

69. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

70. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device.

71. The Magnum Device placed into the stream of commerce by Defendants was defective due to inadequate warnings, because Defendants knew or should have known that the Magnum Device could fail early in patients and therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device with the attendant risks of complications and death from such further surgery, but failed to give consumers adequate warning of such risks.

72. The Magnum Device is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, *inter alia,* the propensity of the Magnum Device to loosen and cause serious pain and necessitate additional surgery as well its propensity to generate metal debris resulting in metallosis and increased cobalt and chromium levels and damage to tissues and bone in patients.

73. Further, the Magnum Device placed into the stream of commerce by Defendants was surgically implanted in a manner reasonably anticipated by Defendants.

74. Defendants are strictly liable for Plaintiff's injuries in the following ways:

(a) Defendants failed to warn and place adequate warnings and instructions on Magnum Device; and

(b) Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of the Magnum Device.

75. As a direct and proximate result of Defendants' placement of the defective Magnum Device into the stream of commerce, Plaintiff experienced and/or will experience

severe harmful effects including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as an additional revision surgery to replace the device with the increased risks of complications and death from such further surgery. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

76. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY AGAINST ALL DEFENDANTS

77. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

78. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device.

79. Defendants expressly warranted that the Magnum Device was a safe and effective hip replacement system and that it would last longer than a traditional polyethylene lined implant and was thus appropriate for young and active patients.

80. Indeed, as set forth in detail above, Defendants made numerous representations about the quality, safety, effectiveness and expected lifetime of the Magnum Device which form express warranties.

81. The Magnum Device placed into the stream of commerce by Defendants did not conform to these express representations because they failed early thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Magnum Device with the attendant risks of complications and death from such further surgery.

82. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Magnum Device, Plaintiff experienced and/or will experience significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty Device, and will continue to suffer such damages in the future.

83. In taking the actions and omissions that caused these damages, Defendants were guilty of malice, oppression and fraud, and Plaintiff is therefore entitled to recover punitive damages.

FOURTH CAUSE OF ACTION
VIOLATION OF THE CONSUMER PROTECTION ACT
AGAINST ALL DEFENDANTS

84. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

85. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Magnum Device as a high-quality, safe and effective hip replacement system to Plaintiff and Plaintiff's physicians.

86. Before they advertised, marketed, sold and represented the Magnum Device that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiff.

87. Plaintiff purchased and used the Magnum Device for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

88. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Magnum Device, and would not have incurred related medical costs and injury.

89. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Magnum Device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

90. Unfair methods of competition or deceptive acts or practices that were prescribed by law, including the following

(a) Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

91. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Magnum Device. Each aspect of Defendants' conduct combined to artificially create sales of the Magnum Device.

92. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion and sale of the Magnum Device.

93. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Magnum Device, and would not have incurred related medical costs.

94. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

95. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

96. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the Consumer Protection Act, Wash. Rev. Code § 19.86.010, *et seq.*

97. Under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants

are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

98. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defice was fit to be used for the purpose for which it was intended, when in fact the Magnum Device was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

99. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

100. Defendants had actual knowledge of the defective and dangerous condition of the Magnum Device and failed to take any action to cure such defective and dangerous conditions.

101. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which hip implant device to use and recommend.

102. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

103. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

104. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

105. As specifically described in detail above, Defendants knew that the Magnum Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

106. As a direct and proximately result of Defendants' representations, Plaintiff has experienced and/or will experience significant damages, including but not limited to permanent physical injury, economic loss, pain and suffering and the need for revision surgery to repair the physical damage to Plaintiff caused by the Magnum Device.

FIFTH CAUSE OF ACTION
NEGLIGENCE
AGAINST ALL DEFENDANTS

107. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

108. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Magnum Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

109. Defendants failed to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the Magnum Device into interstate commerce in that Defendants

knew or should have known that those individuals that had the device surgically implanted were at risk for suffering harmful effects from it, including but not limited to, partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the increased risks of complications and death from such further surgery.

110. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Negligently designing the Magnum Device with excessive or inadequate clearance between the "ball" and "socket"components;

(b) Negligently designing the Magnum Device in such a way that it produces excessive wear thereby causing metal debris;

(c) Designing, manufacturing, producing, creating, and/or promoting the Magnum Device without adequately, sufficiently, or thoroughly testing it, including both pre-market testing and post-market surveillance;

(d) Not conducting sufficient testing programs to determine whether or not the aforesaid Magnum Device was safe for use;

(e) Not conducting sufficient testing programs to determine whether or not the Magnum Device had optimal and safe clearance;

(f) Selling the Magnum Device without making proper and sufficient tests to determine the dangers to its users;

(g) Negligently failing to adequately and correctly warn Plaintiff or Plaintiff's physicians, hospitals and/or healthcare providers of the dangers of Magnum Device, including:

(1) Negligently failing to warn of an increased risk of metallosis and/or metal poisoning;

(2) Negligently failing to warn of an increased risk of elevated cobalt and chromium levels;

(3) Negligently failing to warn of an increased risk of premature failure resulting in necessary revision surgery;

(4) Negligently failing to warn of an increased risk of damage to surrounding tissue, bone, and/or nerves.

(h) Negligently failing to recall their dangerous and defective Magnum Device at the earliest date that it became known that the device was, in fact, dangerous and defective;

(i) Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably implant the Magnum Device into their patients;

(j) Negligently advertising and recommending the use of the Magnum Device despite the fact that Defendants knew or should have known of its dangerous propensities;

(k) Negligently representing that the Magnum Device was safe for use for its intended purpose, when, in fact, it was unsafe;

(l) Negligently manufacturing the Magnum Device in a manner which was dangerous to those individuals who had it implanted;

(m) Negligently designing the Magnum Device in a manner which was dangerous to those individuals who had it implanted;

(n) Defendants under-reported, underestimated and downplayed the serious dangers associated with the Magnum Device.

(o) Failed to use due care in designing and manufacturing the Magnum Device so as to ensure optimal clearance and reduce the risk of metal wear and metal debris;

(p) Failed to accompany their product with proper warnings;

(q) Failed to accompany their product with proper instructions for use;

(r) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Magnum Device;

(s) Were otherwise careless and/or negligent.

111. Despite the fact that Defendants knew or should have known that the Magnum Device caused harm to individuals that had the device surgically implanted, Defendants continued to market, manufacture, distribute and/or sell the Magnum Device.

112. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

113. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and economic loss which Plaintiff has suffered and/or will continue to suffer.

114. By reason of the foregoing, Plaintiff experienced and will continue to experience severe harmful effects as a result of the Defendants' negligence as set forth above.

115. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

116. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION
AGAINST ALL DEFENDANTS

117. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

118. Defendants supplied false information to the public, to Plaintiff and to Plaintiff's physicians regarding the high-quality, safety and effectiveness of the Magnum Device.

Defendants provided this false information to induce the public, Plaintiff and Plaintiff's physicians to purchase and implant a Magnum Device.

119. Defendants supplied through their sales brochures, false information to the public, to Plaintiff and to Plaintiff's physicians regarding the high-quality, safety and effectiveness of the Device, including, statements of low wear, excellent stability, optimal clearance, 99.2% survivorship rate, revision rates of less than 2.5% and superiority over other metal-on-metal hip implants. Defendants provided this false information to induce the public, Plaintiff and Plaintiff's physicians to purchase and implant an M2a Magnum Device.

120. Defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the implant would induce Plaintiff and Plaintiff's physicians to purchase and use a Magnum Device was false and misleading.

121. Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Magnum Device.

122. Plaintiff and Plaintiff's physicians relied on the false information supplied by Defendants to Plaintiff's detriment by causing the Magnum Device to be purchased and implanted in Plaintiff.

123. Plaintiff and Plaintiff's physicians were justified in their reliance on the false information supplied by Defendants regarding the purported high-quality, safety and effectiveness of the Magnum Device.

124. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff experienced and/or will experience significant damages, including but not limited to

permanent physical injury, economic loss, pain and suffering and the need revision surgery to repair the physical damage to Plaintiff caused by the Magnum Device.

125. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AGAINST ALL DEFENDANTS

126. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

127. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device.

128. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device, Defendants knew the use for which the Magnum Device was intended, and impliedly warranted the Magnum Device to be of merchantable quality.

129. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Magnum Device was of merchantable quality.

130. Contrary to Defendants' implied warranties, the Magnum Device was not of merchantable quality or safe for the ordinary purposes for which it was to be used, because the Magnum Device was unreasonably dangerous and/or not reasonably fit for its intended, anticipated or reasonably foreseeable use as described above.

131. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the Magnum Device, Plaintiff experienced and/or will experience significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

132. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AGAINST ALL DEFENDANTS

133. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

134. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device.

135. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Magnum Device, Defendants knew the use for which the Magnum Device was intended, and impliedly warranted the Magnum Device to be of safe for such use.

136. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Magnum Device was safe for its intended use.

137. Contrary to Defendants' implied warranties, the Magnum Device was not of safe for its intended use or fit for the particular purpose for which it was designed, manufactured, tested, distributed or sold – for use and implantation as a total hip replacement system, because the Magnum Device was unreasonably dangerous and/or not reasonably fit for its intended, anticipated or reasonably foreseeable use as described above.

138. As a direct and proximate result of Defendants' breach of implied warranties regarding the safety and effectiveness of the Magnum Device, Plaintiff experienced and/or will experience significant damages, including but not limited to physical injury, economic loss, pain and suffering, and the need for further surgery to replace the faulty device, and will continue to suffer such damages in the future.

139. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting

recipients of Defendants' Magnum Device. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for his injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, past and future lost income, loss of future earning capacity, permanent disability, including permanent instability and loss of balance, and pain and suffering.

3. Double or triple damages as allowed by law;

4. Attorneys' fees, expenses, and costs of this action;

5. Punitive damages, in an amount to be determined at trial;

6. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

7. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: June 13, 2013

Respectfully submitted,

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